CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence, including recited attachments, is being electronically transmitted to the Commissioner for Patents in the United States Patent and Trademark Office on the date below:

Date: December 28, 2010 Name: Richard E. Stanley, Jr. Signature: /Richard E. Stanley, Jr./ Reg. No. 45,662

Our Case No. 8627-1391
Client Ref. No. PA-5511-PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David G. Burton et al.

Serial No.: 10/593,376

Filing Date: July 9, 2007

For: MEDICAL BALLOON WITH ENLARGED TRANSITIONAL RADII

Examiner: Sarah K. Webb

Group Art Unit No.: 3731

Confirmation No.: 8852

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated August 30, 2010, Applicants submit this Appeal Brief in support of the appeal of the rejection of claims 1, 3-4, 12-16, 22 and 24-25. Applicants' claims have been rejected twice, and thus, Applicants are entitled to the present appeal. 37 CFR § 41.31(a). It is respectfully submitted that the rejection of claims 1, 3-4, 12-16, 22 and 24-25 should be reversed for the following reasons.

I. Real Party in Interest

The real party in interest in the present appeal is Cook Incorporated, the assignee of the entire right, title and interest in the application.

II. Related Appeals and Interferences

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned or Cook Inc. "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

III. Status of Claims

Claims 1, 3-4, 12-16, 22 and 24-25 are currently pending.

All pending claims have been rejected.

All pending claims are being appealed in this appeal.

IV. Status of Amendments

Claims 1, 3-4, 22 and 24-25 were amended on December 9, 2010 after the Notice of Appeal was filed and before the filing of this appeal brief in order to address the Examiner's rejections under 35 U.S.C. § 112 ¶ 2. On December 16, 2010, the Examiner represented in a phone call that the December 9 amendments overcome the rejections under 35 U.S.C. § 112 ¶ 2. All other claim amendments have previously been considered by the Examiner.

V. Summary of Claimed Subject Matter

The claimed invention relates to a medical balloon 210 with enlarged radii 254, 260, 265, 270 at the working length-to-taper transition 250, 252 and the taper-to-neck transition 251, 253. (¶ [0036). The enlarged radii 254, 260, 265, 270 provide smooth transitions from the working length 235 to the taper 225, 230 and from the taper 225, 230 to the neck 247, 248. (¶ [0034). As a result of the smooth transitions, lower forces are required to withdraw the balloon catheter 200 through a delivery sheath or other conduit. (¶ [0044]). This advantage solves a number of potential problems. Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to pull back through a conduit after use.

(¶ [0011]). This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]). The balloon catheter 200 may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon 210. (¶ [0044]). The elements of independent claims 1 and 22 are recited below with citations to the preferred embodiments described in the specification.

1. (previously presented) A dilation catheter 200 comprising:

an elongate catheter body 205 with at least one lumen 216; and (Figure 2)

a medical balloon 210 disposed about a portion of the elongate catheter body 205 in fluid communication with the lumen 216, the medical balloon 210 comprising: (Figure 2)

a proximal region 230 and a distal region 225; (Figure 2)

a balloon working length 235 intermediate the proximal region 230 and the distal region 225; (Figure 2)

a proximal working length-to-taper transition 252; (Figure 2)

wherein the proximal working length-to-taper transition 252 comprises a radius 265 before inflation from: (Figure 2)

0.97 to 3.3 mm when the balloon 210 has a working length 235 diameter of about 3 mm, (¶ [0046])

1.8 to 4.7 mm when the balloon 210 has a working length 235 diameter of about 4 mm, (¶ [0046])

2.4 to 6.4 mm when the balloon 210 has a working length 235 diameter of about 5 mm, (¶ [0046])

3.5 to 8.3 mm when the balloon 210 has a working length 235 diameter of about 6 mm, (¶ [0046])

4.8 to 10.2 mm when the balloon 210 has a working length 235 diameter of about 7 mm, (¶ [0046])

6.2 to 11.4 mm when the balloon 210 has a working length 235 diameter of about 8 mm, (¶ [0046])

6.7 to 13.3 mm when the balloon 210 has a working length 235 diameter of about 9 mm, (¶ [0046])

8.1 to 15.2 mm when the balloon 210 has a working length 235 diameter of about 10 mm, (¶ [0046])

9.1 to 17.1 mm when the balloon 210 has a working length 235 diameter of about 11 mm, (¶ [0046])

9.9 to 19.1 mm when the balloon 210 has a working length 235 diameter of about 12 mm, (¶ [0046])

11.2 to 22.9 mm when the balloon 210 has a working length 235 diameter of about 14 mm, or (¶ [0046])

13.3 to 25.4 mm when the balloon 210 has a working length 235 diameter of about 15 mm (¶ [0046]).

22. (previously presented) A method of reducing the force required to remove a dilation catheter from a conduit, comprising:

(a) inserting the dilation catheter 200 through the conduit, so a medical balloon 210 disposed on the catheter 200 emerges from the conduit, wherein the dilation catheter 200 includes an elongate catheter body 205, the medical balloon 210 comprising: (¶¶ [0002]-[0007])

a proximal region 230 and a distal region 225; (Figure 2)

a balloon working length 235 intermediate the proximal region 230 and the distal region 225; (Figure 2)

a proximal working length-to-taper transition 252; (Figure 2)

wherein the proximal working length-to-taper transition 252 comprises a radius 265 before inflation from: (Figure 2)

0.97 to 3.3 mm when the balloon 210 has a working length 235 diameter of about 3 mm, (¶ [0046])

1.8 to 4.7 mm when the balloon 210 has a working length 235 diameter of about 4 mm, (¶ [0046])

2.4 to 6.4 mm when the balloon 210 has a working length 235 diameter of about 5 mm, (¶ [0046])

3.5 to 8.3 mm when the balloon 210 has a working length 235 diameter of about 6 mm, (¶ [0046])

4.8 to 10.2 mm when the balloon 210 has a working length 235 diameter of about 7 mm, (¶ [0046])

6.2 to 11.4 mm when the balloon 210 has a working length 235 diameter of about 8 mm, (¶ [0046])

6.7 to 13.3 mm when the balloon 210 has a working length 235 diameter of about 9 mm, (¶ [0046])

8.1 to 15.2 mm when the balloon 210 has a working length 235 diameter of about 10 mm, (¶ [0046])

9.1 to 17.1 mm when the balloon 210 has a working length 235 diameter of about 11 mm, (¶ [0046])

9.9 to 19.1 mm when the balloon 210 has a working length 235 diameter of about 12 mm, (¶ [0046])

11.2 to 22.9 mm when the balloon 210 has a working length 235 diameter of about 14 mm, or (¶ [0046])

13.3 to 25.4 mm when the balloon 210 has a working length 235 diameter of about 15 mm; (¶ [0046])

(b) inflating the balloon 210 by providing a fluid to a catheter lumen 216 in fluid communication with the balloon 210; (¶¶ [0002]-[0007])

(c) deflating the balloon 210; and (¶¶ [0044]-[0045])

(d) applying a force to the dilation catheter 200, so the balloon 210 is withdrawn through the conduit (¶¶ [0044]-[0045]).

VI. Grounds of Rejection to be Reviewed on Appeal

A. The Examiner has rejected claims 1, 3-4, 12-16, 22 and 24-25 pursuant to 35 U.S.C. § 112 ¶ 2.

B. The Examiner has rejected claims 1, 3-4, 12-16, 22 and 24-25 as being unpatentable pursuant to 35 U.S.C. § 103(a) over U.S. Patent No. 2003/0139762 ("Lee") in view of U.S. Patent No. 5,797,878 ("Bleam").

VII. Argument

A. Claims 1, 3-4, 12-16, 22 and 24-25 are not indefinite.

Applicants amended claims 1, 3-4, 22 and 24-25 on December 9, 2010 after the Notice of Appeal was filed and before the filing of this appeal brief in order to address the Examiner's rejections under 35 U.S.C. § 112 ¶ 2. On December 16, 2010, the Examiner represented in a phone call that the December 9 amendments overcome the rejections under 35 U.S.C. § 112 ¶ 2. Thus, Applicants understand that these rejections are now moot and the Examiner will be withdrawing the § 112 rejections.

B. Claims 1, 3-4, 12-16, 22 and 24-25 are not obvious over Lee in view of Bleam.

Applicant seeks review of the Examiner's rejections of claims 1, 3-4, 12-16, 22 and 24-25 as being unpatentable under 35 U.S.C. § 103(a) over Lee in view of Bleam. The ultimate issue before the Board is whether the prior art as combined discloses all of the limitations of Applicants' claims and whether there would have been an apparent reason to combine Lee and Bleam to achieve Applicants' claim limitations. Applicants respectfully submit that the Examiner has not established that Applicants' claim limitations are obvious in view of Lee and Bleam, and therefore, the Examiner's rejections should be reversed.

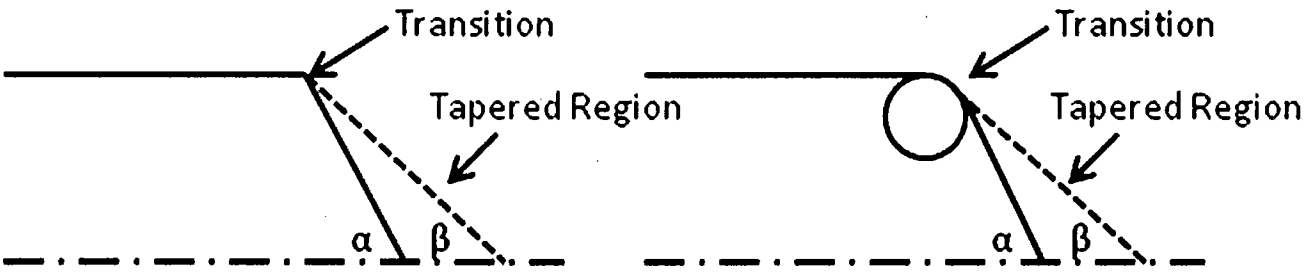
The claimed invention relates to a medical balloon with enlarged radii at the working length-to-taper transition and the taper-to-neck transition. The enlarged radii

provide smooth transitions from the working length to the taper and from the taper to the neck. As a result of the smooth transitions, lower forces are required to withdraw the balloon catheter through a delivery sheath or other conduit. (¶ [0044]). This advantage solves a number of potential problems. Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to pull back through a conduit after use. This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]). The claimed balloon catheter may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon. (¶ [0044]).

The specific transitions that are covered by the claims are shown in Figure 2 of Applicants' specification. For example, claim 1 requires the "proximal working length-to-taper transition" to be a radius within a specified range. The proximal working length-to-taper transition is, as its name suggests, the transition between the working length and the taper. For example, in Figure 2, the working length is identified as 235; the proximal conical region, or taper, is identified as 230; the proximal working length-to-taper transition is identified as 252; and the radius of the working length-to-taper transition is identified as 265. Thus, claim 1 relates specifically to a radius at transition 252 as shown in Figure 2. Accordingly, the claimed inventions relate to the transitions to the tapered regions, not to the shape of the tapered regions themselves.

Turning to the prior art of record, neither Lee nor Bleam disclose the enlarged radii claimed by Applicants. Unlike Applicants' claims, Lee and Bleam only relate to the shape of the tapered regions and not to the transitions to the tapered regions. Thus, Lee and Bleam relate to an entirely different region of the balloon than Applicants' claims. The Examiner has suggested that Applicants' distinction is merely an argument over semantics. (Final Office Action dated 8/30/2010 at 3). However, Lee and Bleam do not merely use different words to describe the same structure as Applicants' claims. Instead, Lee and Bleam and Applicants' claims relate to different parts of a balloon. The sketch below may be helpful in recognizing the structural differences between Applicants' claims and Lee and Bleam. As noted above, Lee and Bleam relate to the

tapered regions, which as shown can be changed from taper α to taper β. However, Applicants' claims relate to the transition to the tapered region, which could be sharp as shown on the left or enlarged as shown on the right. However, as illustrated, the fact that the taper can be changed from α to β has no impact on the transition to the taper. As shown on the left, the transition is still sharp even though the taper changes from α to β. Likewise, the enlarged transition on the right does not change whether the taper is α or β.



In response to the Examiner's rejection, Applicants previously submitted the declaration of David G. Burton dated June 7, 2010 as evidence of non-obviousness, which is included in the evidence appendix herein. In light of Mr. Burton's declaration, Applicants respectfully submit that the prior art of record does not disclose all of the limitations of Applicants' claims and Applicants' claims would not be readily apparent from the prior art.

As explained by Mr. Burton, Lee relates to a method of making an angioplasty balloon. (Burton 6/7/2010 Decl. ¶ 3). Lee claims that an advantage of the manufacturing method is that low profile and flexibility are achieved. (¶ [0027], line 9; Burton 6/7/2010 Decl. ¶ 3). Specifically, Lee's manufacturing method involves inserting an inner tube 106 through a shortened outer tube 102 to form a slug 100, as shown in Figure 2. (¶ [0025]; Burton 6/7/2010 Decl. ¶ 3). The slug 100 is then placed in a mold and heated and pressurized to form a balloon. (¶ [0025]; Burton 6/7/2010 Decl. ¶ 3). In the finished balloon, the shortened outer tube 102 forms the working length 44, and the inner tube 106 forms the proximal and distal tapers 48, 50. (¶ [0025], lines 13-17; Burton 6/7/2010 Decl. ¶ 3). As a result, less tube material is provided to the tapers 48, 50 than to the working length 44. (¶ [0027], lines 1-3; Burton 6/7/2010 Decl. ¶ 3).

By contrast, the claimed inventions relate to a medical balloon with enlarged radii at the working length-to-taper transition and the taper-to-neck transition. (Burton 6/7/2010 Decl. ¶ 4). The enlarged radii provide smooth transitions from the working length to the taper and from the taper to the neck. (Burton 6/7/2010 Decl. ¶ 4). As a result of the smooth transitions, lower forces are required to withdraw the balloon catheter through a delivery sheath or other conduit. (¶ [0044]; Burton 6/7/2010 Decl. ¶ 4). This advantage solves a number of potential problems. (Burton 6/7/2010 Decl. ¶ 4). Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to pull back through a conduit after use. (Burton 6/7/2010 Decl. ¶ 4). This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]; Burton 6/7/2010 Decl. ¶ 4). The claimed balloon catheter may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon. (¶ [0044]; Burton 6/7/2010 Decl. ¶ 4).

As Mr. Burton explains, Lee does not relate to the balloon profile that the Applicants developed. (Burton 6/7/2010 Decl. ¶ 5). As explained above, Lee's balloon has tapers with a thinner wall thickness than the working length. (Burton 6/7/2010 Decl. ¶ 5). By contrast, the claimed inventions relate to enlarged radii at the transitions between the working length and the tapers, and the transitions between the tapers and the necks. (Burton 6/7/2010 Decl. ¶ 5). Not only is Lee related to an entirely different geometry than claimed inventions, but Lee does not even mention the transitions between the tapers and the working length and the necks. (Burton 6/7/2010 Decl. ¶ 5). Since Lee does not even refer to the relevant transitions, Lee also fails to specify any of the specific radii that Applicants discovered for the transitions. (Burton 6/7/2010 Decl. ¶ 5).

While Bleam generally recognizes the desirability of minimizing cross and recross forces (col. 2:31-34), Bleam solves this problem in a different way than the claimed inventions do. (Burton 6/7/2010 Decl. ¶ 6). The solution offered by Bleam is to change the angle α of the taper to make the tapered portions of the balloon more tapered. (Col. 5:53-55; 5:62-6:6; Burton 6/7/2010 Decl. ¶ 6). Bleam's preferred taper angle α is between 7° and 20°, 9° and 12°, or 10° and 11°. (Col. 6:52-56; Burton

6/7/2010 Decl. ¶ 6). However, this is not the solution that Applicants developed. (Burton 6/7/2010 Decl. ¶ 6). Instead, as noted above, the claimed inventions relate to a balloon where the radii at the transitions between the working length and the taper and between the taper and the neck region are enlarged—irrespective of the angle of the taper. (Burton 6/7/2010 Decl. ¶ 6). Like Lee, Bleam does not even mention the transitions that the claimed inventions relate to. (Burton 6/7/2010 Decl. ¶ 6). Because Bleam doesn't mention the relevant transitions, Bleam also does not specify any dimensions for the transitions, much less the specific radii that Applicants discovered. (Burton 6/7/2010 Decl. ¶ 6).

In addition to the fact that the written descriptions of Lee and Bleam do not disclose anything about the transitions between the tapers and the working length and the necks, the figures of Lee and Bleam do not provide a suggestion to achieve the claimed inventions. (Burton 6/7/2010 Decl. ¶ 7). As noted in the specification of the application, the transitions of an inflated balloon may actually look smooth; however when the balloon is deflated, the differences are significant. (¶ [0047]; Burton 6/7/2010 Decl. ¶ 7). Indeed, the courts and the Patent Office have repeatedly warned against the use of figures for scaling undefined features. *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) ("The district court erred in not properly applying the principles set forth in our prior precedents that arguments based on drawings not explicitly made to scale in issued patents are unavailing."); MPEP § 2125 ("PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE . . . When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.").

Indeed, not only does Lee and Bleam not disclose that the radii may be enlarged at the transitions to reduce the force needed to withdraw the balloon, but Lee and Bleam do not disclose the actual radii that are specified by claims 1, 3-4 and 22-25. These are specific radii that Applicants discovered that are not disclosed or suggested by the prior art. Moreover, the prior art does not disclose or suggest the specific relationships defined in claims 12-16. For example, in claims 14 and 15, the proximal and distal taper-to-neck radii are the same as each other and the proximal and distal

working length-to-taper radii are different than the taper-to-neck radii. Additionally, in claim 16 the proximal working length-to-taper radius is different than the distal working length-to-taper radius.

Accordingly, it is respectfully submitted that neither Lee nor Bleam disclose all of the limitations of Applicants' claims, and there is no suggestion to modify the prior art to achieve Applicants' claim limitations. Specifically, Lee and Bleam do not even mention the transitions between the taper and the working length and the necks that the claimed inventions relate to. Moreover, Lee and Bleam fail to disclose the specific radii that have been claimed for the transitions. For at least these reasons, the combination of Lee and Bleam does not render obvious claims 1, 3-4, 12-16, 22 and 24-25, and the Examiner's rejections should be reversed.

VIII. Conclusion

Applicants respectfully submit that claims 1, 3-4, 12-16, 22 and 24-25 are allowable over the prior art of record. As argued above, Applicants submit that the prior art of record does not disclose all of the limitations of Applicants' claims, and there would have been no apparent reason to combine the prior art of record in the manner that the Examiner has proposed in order to achieve the claimed inventions. Accordingly, Applicants request that the Examiner's rejections of claims 1, 3-4, 12-16, 22 and 24-25 be reversed and Applicants' application be allowed as presented.

Respectfully submitted,

/Richard E. Stanley, Jr./
Richard E. Stanley, Jr.
Registration No. 45,662
Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200

Claims Appendix

1. (previously presented) A dilation catheter comprising:

an elongate catheter body with at least one lumen; and

a medical balloon disposed about a portion of the elongate catheter body in fluid communication with the lumen, the medical balloon comprising:

a proximal region and a distal region;

a balloon working length intermediate the proximal region and the distal region;

a proximal working length-to-taper transition;

wherein the proximal working length-to-taper transition comprises a radius before inflation from:

0.97 to 3.3 mm when the balloon has a working length diameter of about 3 mm,

1.8 to 4.7 mm when the balloon has a working length diameter of about 4 mm,

2.4 to 6.4 mm when the balloon has a working length diameter of about 5 mm,

3.5 to 8.3 mm when the balloon has a working length diameter of about 6 mm,

4.8 to 10.2 mm when the balloon has a working length diameter of about 7 mm,

6.2 to 11.4 mm when the balloon has a working length diameter of about 8 mm,

6.7 to 13.3 mm when the balloon has a working length diameter of about 9 mm,

8.1 to 15.2 mm when the balloon has a working length diameter of about 10 mm,

9.1 to 17.1 mm when the balloon has a working length diameter of about 11 mm,

9.9 to 19.1 mm when the balloon has a working length diameter of about 12 mm,

11.2 to 22.9 mm when the balloon has a working length diameter of about 14 mm, or

13.3 to 25.4 mm when the balloon has a working length diameter of about 15 mm.

2. (canceled).

3. (previously presented) The dilation catheter of claim 1, where the radius is from:

1.3 to 3.3 mm when the balloon has a working length diameter of about 3 mm,

2.5 to 4.7 mm when the balloon has a working length diameter of about 4 mm,

3.2 to 6.4 mm when the balloon has a working length diameter of about 5 mm,

4.7 to 8.3 mm when the balloon has a working length diameter of about 6 mm,

6.4 to 10.2 mm when the balloon has a working length diameter of about 7 mm,

8.3 to 11.4 mm when the balloon has a working length diameter of about 8 mm,

8.9 to 13.3 mm when the balloon has a working length diameter of about 9 mm,

10.8 to 15.2 mm when the balloon has a working length diameter of about 10 mm,

12.1 to 17.1 mm when the balloon has a working length diameter of about 11 mm,

13.3 to 19.1 mm when the balloon has a working length diameter of about 12 mm,

14.9 to 22.9 mm when the balloon has a working length diameter of about 14 mm, or

17.8 to 25.4 mm when the balloon has a working length diameter of about 15 mm.

4. (previously presented) The dilation catheter of claim 1, where the radius is:

about 2.5 mm when the balloon has a working length diameter of about 3 mm,

about 3.2 mm when the balloon has a working length diameter of about 4 mm,

about 4.7 mm when the balloon has a working length diameter of about 5 mm,

about 6.4 mm when the balloon has a working length diameter of about 6 mm,

about 8.3 mm when the balloon has a working length diameter of about 7 mm,

about 8.9 mm when the balloon has a working length diameter of about 8 mm,

about 10.8 mm when the balloon has a working length diameter of about 9 mm,

about 12.1 mm when the balloon has a working length diameter of about 10 mm,

about 13.3 mm when the balloon has a working length diameter of about 11 mm,

about 14.9 mm when the balloon has a working length diameter of about 12 mm,

about 17.8 mm when the balloon has a working length diameter of about 14 mm, or

about 19.1 mm when the balloon has a working length diameter of about 15 mm.

5-11. (canceled).

12. (previously presented) The dilation catheter of claim 1, where the proximal working length-to-taper radius is substantially equal to a distal working length-to-taper radius.

13. (previously presented) The dilation catheter of claim 1, where a proximal taper-to-neck radius, the proximal working length-to-taper radius, a distal taper-to-neck radius, and a distal working length-to-taper radius are substantially equal.

14. (previously presented) The dilation catheter of claim 1, where a proximal taper-to-neck radius and a distal taper-to-neck radius are substantially equal to each other.

15. (previously amended) The dilation catheter of claim 14, where the proximal working length-to-taper radius and a distal working length-to-taper radius are different from the proximal taper-to-neck radius and the distal taper-to-neck radius.

16. (previously presented) The dilation catheter of claim 1, where the proximal working length-to-taper radius and a distal working length-to-taper radius are different.

17-21. (canceled).

22. (previously presented) A method of reducing the force required to remove a dilation catheter from a conduit, comprising:

(a) inserting the dilation catheter through the conduit, so a medical balloon disposed on the catheter emerges from the conduit, wherein the dilation catheter includes an elongate catheter body, the medical balloon comprising:

a proximal region and a distal region;

a balloon working length intermediate the proximal region and the distal region;

a proximal working length-to-taper transition;

wherein the proximal working length-to-taper transition comprises a radius before inflation from:

0.97 to 3.3 mm when the balloon has a working length diameter of about 3 mm,

1.8 to 4.7 mm when the balloon has a working length diameter of about 4 mm,

2.4 to 6.4 mm when the balloon has a working length diameter of about 5 mm,

3.5 to 8.3 mm when the balloon has a working length diameter of about 6 mm,

4.8 to 10.2 mm when the balloon has a working length diameter of about 7 mm,

6.2 to 11.4 mm when the balloon has a working length diameter of about 8 mm,

6.7 to 13.3 mm when the balloon has a working length diameter of about 9 mm,

8.1 to 15.2 mm when the balloon has a working length diameter of about 10 mm,

9.1 to 17.1 mm when the balloon has a working length diameter of about 11 mm,

9.9 to 19.1 mm when the balloon has a working length diameter of about 12 mm,

11.2 to 22.9 mm when the balloon has a working length diameter of about 14 mm, or

13.3 to 25.4 mm when the balloon has a working length diameter of about 15 mm;

(b) inflating the balloon by providing a fluid to a catheter lumen in fluid communication with the balloon;

(c) deflating the balloon; and

(d) applying a force to the dilation catheter, so the balloon is withdrawn through the conduit.

23. (canceled).

24. (previously presented) The method of claim 22, where the radius is from:

1.3 to 3.3 mm when the balloon has a working length diameter of about 3 mm,

2.5 to 4.7 mm when the balloon has a working length diameter of about 4 mm,

3.2 to 6.4 mm when the balloon has a working length diameter of about 5 mm,

4.7 to 8.3 mm when the balloon has a working length diameter of about 6 mm,

6.4 to 10.2 mm when the balloon has a working length diameter of about 7 mm,

8.3 to 11.4 mm when the balloon has a working length diameter of about 8 mm,

8.9 to 13.3 mm when the balloon has a working length diameter of about 9 mm,

10.8 to 15.2 mm when the balloon has a working length diameter of about 10 mm,

12.1 to 17.1 mm when the balloon has a working length diameter of about 11 mm,

13.3 to 19.1 mm when the balloon has a working length diameter of about 12 mm,

14.9 to 22.9 mm when the balloon has a working length diameter of about 14 mm, or

17.8 to 25.4 mm when the balloon has a working length diameter of about 15 mm.

25. (previously presented) The method of claim 22, where the radius is:

about 2.5 mm when the balloon has a working length diameter of about 3 mm,

about 3.2 mm when the balloon has a working length diameter of about 4 mm,

about 4.7 mm when the balloon has a working length diameter of about 5 mm,

about 6.4 mm when the balloon has a working length diameter of about 6 mm,

about 8.3 mm when the balloon has a working length diameter of about 7 mm,

about 8.9 mm when the balloon has a working length diameter of about 8 mm,

about 10.8 mm when the balloon has a working length diameter of about 9 mm,

about 12.1 mm when the balloon has a working length diameter of about 10 mm,

about 13.3 mm when the balloon has a working length diameter of about 11 mm,

about 14.9 mm when the balloon has a working length diameter of about 12 mm,

about 17.8 mm when the balloon has a working length diameter of about 14 mm, or

about 19.1 mm when the balloon has a working length diameter of about 15 mm.

26. (canceled).

Evidence Appendix

Declaration of David G. Burton dated June 7, 2010.

Related Proceedings Appendix

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned or Cook Inc. "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal." As such, there are no "decisions rendered by a court or the Board in any proceeding" to submit.